

Garlock, Inc., 721 F.2d 1540, 1554 (Fed.Cir.1983); *see*, also, *Ex Parte Standish*, Appeal No. 1987-0178 (BPAI 1988) (Examiner's finding of anticipation improper when because whether a claimed feature was shown in a prior art reference was "not entirely clear.")

I. Pinchuk

The Examiner rejected claims 74, 76-78, and 80-82 under 35 U.S.C. §102(b) as being anticipated by Pinchuk.

Claims 74, 76-78, and 80-82 cover articles including a polyamide having a tensile strength of at least about 21,000 psi. Pinchuk does not disclose such articles. Rather, Pinchuk discloses balloon catheters in which the balloon-portion is reported to:

have a *calculated tensile strength* of between about 15,000 and about 35,000 psi and above, preferably between about 20,000 and about 32,000 psi. (Pinchuk col. 11, lines 13-21, emphasis added).

It is unclear to Applicants what Pinchuk means by a "calculated" tensile strength, or how this might compare to the tensile strength defined in Applicants' specification in, for example, page 10, line 30 to page 11, line 2. As a result, for at least this reason, the Examiner has not met his burden in establishing that Pinchuk anticipates claims 74, 76-78, and 80-82.¹

In view of the foregoing, Applicants request reconsideration and withdrawal of the rejection of claims 74, 76-78, and 80-82 under 35 U.S.C. §102(b) as being anticipated by Pinchuk.

II. Sahatjian

The Examiner rejected claims 84, 86, 88, 89, and 91 under 35 U.S.C. §102(b) as being anticipated by Sahatjian.

Claims 84, 86, 88, 89 and 91 cover articles including a polyamide having a hoop stress of at least about 3300 psi.

¹ Applicants presented this argument before, and the Examiner failed to address the argument. Applicants believe that the Examiner is obliged to address this argument if he is to maintain this rejection.

Sahatjian does not disclose such articles. Rather, Sahatjian discloses blends of polyolefins (*e.g.*, polyethylene, polypropylene, polybutylene and copolymers thereof) and polyesters for dilatation balloons, and discloses suitable polyolefins and polyesters for forming blends. (*See, e.g.*, Sahatjian, col. 3, lines 4-7, lines 14-15, and lines 37-43). Sahatjian does disclose, in particular embodiments, balloons produced using known methods for blending incompatible polymers (*e.g.*, polyesters and polyolefins) using condensation polymers. (*See, e.g., id.*, col. 3, lines 48-63.) In some cases, the condensate polymer may be a polyamide. (*See, e.g., id.*) However, Sahatjian does not provide any information about the hoop stress characteristics of balloons produced by his blending method. Instead, Sahatjian provides a lengthy discussion and numerous examples (including hoop stress characteristics) for balloons made of materials *other than polyamides*. (*See, e.g.*, Sahatjian, Examples I and II, Table 1, and FIG. 4.) Thus, contrary to the Examiner's assertion, Sahatjian does not disclose a balloon *which includes a polyamide* (in the form of a condensate polymer or otherwise) with a hoop stress greater than about 36,000 psi. Applicants therefore request reconsideration and withdrawal of the rejection of claims 84, 86, 88, 89, and 91 under 35 U.S.C. §102(b) as being anticipated by Sahatjian.²

35 U.S.C. §103(a) Rejection

Pinchuk in view of Sahatjian

The Examiner rejected claims 79 and 83 under 35 U.S.C. §103(a) as being unpatentable over Pinchuk in view of Sahatjian.

But, there is not suggestion to combine these references. Pinchuk discloses balloon catheters made out of polyamides. (Pinchuk, col. 10, lines 30-31). According to Pinchuk, there are advantageous properties of polyamides used in this fashion. (*See, e.g., id.*, col. 10 lines 30-61). In contrast, Sahatjian teaches the use of a balloon "composed predominantly of a blend of crystallizeable resin and [an] ... additive polymer, *e.g.*, polyolefin, that interrupts the crystalline

² Applicants presented this argument before, and the Examiner failed to address the argument. Applicants believe that the Examiner is obliged to address this argument if he is to maintain this rejection.

network of the crystalline resin in the final product. " (Sahatjian, abstract). Sahatjian further states that:

[i]n particular embodiments, the balloon is composed of a minor amount of heterogeneous, preblended, polyolefin (e.g. polyethylene) and a polyester (e.g. PET); the preblend is then blended with a relatively high molecular weight PET.... Suitable polyolefins and polyesters for forming the preblend and methods for blending incompatible polymers are known and are discussed in U.S. Pat. No. 4,444,817 entitled "Process for Making Laminar Articles of Polyolefins and Condensation Polymer", by Subramanian, the entire contents of which are hereby incorporated by reference. ...*The condensation polymers may be a polyamide, or polyester such as PET or polycarbonates.* (Id., col. 3, lines 48-63).

However, as described in detail in the Subramanian patent, U.S. Pat. No. 4,444,817, a condensate polyamide in a polyolefin/polyester blend serves only to allow the blending of the incompatible polyolefin and polyester (col 2, lines 25-42). The blend is composed primarily of the polyolefin and polyester and would not, in general, exhibit the same properties of the polyamide standing alone (*see, e.g.*, col. 5, lines 7-21). One skilled in the art would have recognized that the polyolefin/polyester blend balloon described in Sahatjian would not, in general, exhibit the same advantageous properties as the polyamide balloons described in Pinchuk, and therefore would be incompatible with the device of Pinchuk. Thus a person skilled in the art at the time of the invention would not have combined the balloon of Sahatjian with the device of Pinchuk.

Even if the combination of Pinchuk and Sahatjian were proper, the combined references still do not disclose each and every limitation appearing in claims 79 and 83.

Claims 79 and 83 cover articles including a polyamide having a tensile strength of at least about 21,000 psi. As discussed above, the Examiner has not demonstrated that Pinchuk recites this limitation. Sahatjian makes no mention of tensile strength values, and therefore does not cure this difficulty. Thus Applicants submit that claims 79 and 83 patentably distinguish any combination of Pinchuk and Sahatjian.³

³ Applicants presented this argument before, and the Examiner failed to address the argument. Applicants believe that the Examiner is obliged to address this argument if he is to maintain this rejection.

Neither Pinchuk nor Sahatjian, alone or in combination, discloses or suggests the subject matter covered by claims 79 and 83. There is no suggestion to combine these references to provide such subject matter, and, even if the references were combined, the result would not be the subject matter covered by these claims. Accordingly, Applicants request reconsideration and withdrawal of the rejection of claims 79, and 83 under 35 U.S.C. §103(a).

Sahatjian in view of Pinchuk

The Examiner rejected claims 87 and 90 under 35 U.S.C. §103(a) as being unpatentable over Sahatjian in light of Pinchuk.

Applicants do not concede that the suggested combination of Sahatjian and Pinchuk is proper. However, even if the combination of Pinchuk and Sahatjian were proper, the combined references still do not disclose each and every limitation appearing in claims 87 and 90.

Claims 87 and 90 cover articles including a polyamide having a hoop stress of at least about 3300 psi. As discussed above, the Examiner has not demonstrated that Sahatjian discloses an article including a region that comprises a polyamide having a hoop stress of at least about 3300 psi, as required by the claims. Further, the Examiner, at page 4 of the Office Action, states that Pinchuk fails to teach a balloon that has a hoop stress of at least about 3300 psi. Thus, Applicants submit that claims 87 and 90 patentably distinguish any combination of Pinchuk and Sahatjian.

Neither Sahatjian nor Pinchuk, alone or in combination, discloses or suggests the subject matter covered by claims 87 and 90. There is no suggestion to combine these references to provide such subject matter, and, even if the references were combined, the result would not be the subject matter covered by these claims. Accordingly, Applicants request reconsideration and withdrawal of the rejection of claims 87 and 90 under 35 U.S.C. §103(a).

Pinchuk in view of Wang

The Examiner rejected claims 130 and 131 under 35 U.S.C. §103(a) as being unpatentable over Pinchuk in view of Wang et al., U.S. Patent No. 6,124,007 ("Wang").

Applicants do not concede that the suggested combination of Pinchuk and Wang is proper. However, even if the combination of Pinchuk and Wang were proper, the combined references still do not disclose each and every limitation appearing in claims 130 and 131.

Claims 130 and 131 cover articles including a polyamide having a tensile strength of at least about 21,000 psi. As discussed above, the Examiner has not demonstrated that Pinchuk discloses such an article. Nor does Pinchuk suggest such an article, and Wang does not cure Pinchuk's infirmities.

Neither Pinchuk nor Wang, alone or in combination, discloses or suggests the subject matter covered by claims 130 and 131. There is no suggestion to combine these references to provide such subject matter, and, even if the references were combined, the result would not be the subject matter covered by these claims. Accordingly, Applicants request reconsideration and withdrawal of the rejection of claims 130 and 131 under 35 U.S.C. §103(a).

Conclusion

Applicants believe the application is in condition for allowance, which action is requested.

Please apply any charges or credits to deposit account 06-1050.

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Respectfully submitted,

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